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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,420	01/14/2005	Peter Greasley	ASZD-P01-752	9948

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/521,420	GREASLEY, PETER	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 15-31* is/are pending in the application.

4a) Of the above claim(s) *11,12,15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,17-23 and 25-31* is/are rejected.

7)☒ Claim(s) *24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 January 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 1 to 12 and 15 to 31 are pending in the instant application.

2) Claims 11, 12, 15 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 21 November of 2005. The traversal is on the ground(s) that "the relationship between the compounds of Group II and the compounds identified by the methods of Group I is material, and it is clear that these compounds are one and the same". This is not found persuasive because the claimed process neither makes nor specifically uses the product of invention II. Applicant is further advised that claim 11, for example, can not properly depend from any of claims 1 to 4. A properly dependent claim can not conceivably be infringed without infringing any of the claims from which it depends. See M.P.E.P. 608.01(n)III. The well-known prior art compound CP55940 clearly infringes claim 11, which is a product claim of group II, without infringing any of the analytical or product claims of group I.

The requirement is still deemed proper and is therefore made FINAL.

3) The instant specification does not comply with 37 C.F.R. ɜ 1.77, which requires that:

(a) The elements of the application, if applicable, should appear in the following order:

(1) Utility Application Transmittal Form.

(2) Fee Transmittal Form.

(3) Title of the invention; or an introductory portion stating the name, citizenship, and residence of the applicant, and the title of the invention.

(4) Cross-reference to related applications.

(5) Statement regarding federally sponsored research or development.

(6) Reference to a AMicrofiche appendix.≅ (See ə 1.96 (c)). The total number of microfiche and total number of frames should be specified.

(7) Background of the invention.

(8) Brief summary of the invention.

(9) Brief description of the several views of the drawing.

(10) Detailed description of the invention:

(11) Claim or claims.

(12) Abstract of the Disclosure.

(13) Drawings.

(14) Executed oath or declaration.

(15) Sequence Listing (See ə ə 1.821 through 1.825).

(b) The elements set forth in paragraphs (a)(3) through (a)(5), (a)(7) through (a)(12) and (a)(15) of this section should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase ANot Applicable≅ should follow the section heading. [43 FR 20464, May 11, 1978; 46 FR 2612, Jan. 12, 1981; paras. (h) and (i), 48 FR 2712, Jan. 20, 1983, effective Feb. 27, 1983; revised, 61 FR 42790, Aug. 19, 1996, effective Sept. 23, 1996].

Whereas the instant application contains a figure, there is no description of this drawing in the instant specification. Correction is required.

4) The figure in the instant application does not comply with 37 C.F.R. § 1.84(U)(1), which states that " [where only a single view is used in an application to illustrate the claimed invention, it must not be numbered and the abbreviation "FIG" must not appear".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5) Claims 1 to 10 and 17, 18, 21 to 23 and 25 to 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirements because they encompass subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Whereas the instant specification clearly describes three specific CB1b cannabinoid receptors, each having what is described in line 27 of page 7 of the instant specification as "an increased level of intrinsic activity" relative to the native human CB1b receptor from which they were derived, as well as methods of making and using those three proteins, it does not provide an adequate written description of the genus of proteins encompassed the limitation "constitutively active CB receptor" or the guidance needed to predictability alter any one of the amino acid sequences encoded by the nucleotide sequences presented in SEQ ID NO:2, 3 and 4 of the instant application with any reasonable expectation that an altered protein will retain either the functionality or advantages disclosed for a human CB1b protein of the instant invention.

The limitation "a constitutively active CB receptor" as recited, for example, in claims 1 to 4, encompasses any protein that binds to a canniboid and is activated thereby, and which has a measurable biological activity in the absence of agonist. Whereas this limitation can conceivably encompass an almost unlimited number of protein embodiments, including proteins having little or no structural similarity to one of

the three human CB1 derived proteins described in the instant specification, the instant specification only provides the guidance needed to produce those three proteins described therein. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Because the instant specification does not identify those amino acid residues in SEQ ID NO:1 which are critical to the structural and functional integrity of a receptor protein comprising that sequence, identify a structurally analogous protein for which this information is known and could be applied to the instant protein by extrapolation, or even provide a single working example of an intentionally modified protein of the instant invention lacking the entire amino acid sequence of human CB1 except for the two specific modifications identified therein as an alanine substitution as position 213 or 338 of "the human wild type CB1b receptor", an artisan can not change even a single residue within the amino acid sequence encoded by the nucleotide sequences presented in SEQ ID NO:2, 3 and 4 of the instant application and predict the effects of

that change on the performance of that protein "by resort to known scientific law". Because the instant specification does not disclose the rational behind Applicant's choice of their specific modifications to "the human wild type CB1b receptor" or provide an explanation of some underlying mechanism through which the disclosed modification resulted in "an increased level of intrinsic activity" relative to the native human CB1 receptor an artisan is incapable of making analogous modifications to other cannabinoid receptors with any reasonable expectation of achieving "an increased level of intrinsic activity" relative to a native receptor.

Claim 17 is essentially a single means claim because the only limitations recited therein a functionally defined. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt , 708 F.2d 712,>714 - 715,< 218 USPQ 195>, 197< (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6) Claims 5 to 8, 20, 22, 25 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6.1) Claims 5 and 6 are vague and indefinite because the metes and bounds of the limitation "a variant thereof" are undeterminable. Claims 7 and 8 are vague and indefinite in so far as they depend from claim 5 or 6 for this element.

6.2) Claim 20 is vague and indefinite because there is no antecedent basis for "the method of claim 18".

6.3) Claim 22 is vague and indefinite because there is no antecedent basis for "the isolated nucleic acid according to claim 21" because claim 21 is drawn to "an isolated nucleic acid sequence". This claim is vague and indefinite because the limitations "variant", and "the amino acids located at positions 3:49 and 6:32" each requires a frame of reference and none is provided.

6.4) Claim 25 is vague and indefinite because there is no antecedent basis for "the nucleic acid molecule as claimed in claim 21".

6.5) Claim 28 is vague and indefinite because there is no antecedent basis for "one or both of the natural amino acids at positions 3:49 and 6:32 of the receptor polypeptide" and because the limitation "the amino acids located at positions 3:49 and 6:32" requires a frame of reference and none is provided.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7) Claims 17, 18, 21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

7.1) Claims 17 and 18 encompass a native protein. As indicated by the text in lines 4 and 5 on page 7 of the instant specification, "the CB receptor" "possesses a low level of intrinsic activity, i.e., an activity that occurs in the absence of an agonist". Therefore, claims 17 and 18 encompass a CB receptor protein as it occurs in nature because CB receptors are naturally constitutively active.

7.2) Claim 21 is drawn to a nucleic and "sequence". Because a "nucleic acid sequence" is a property of a nucleic acid molecule and not a material entity in and of itself, a nucleic acid sequence is not subject to patentability.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

8) Claims 1 to 6, 9, 10, 17, 18 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by the MacLennan et al. publication (British Journal of Pharmacology 124:619-622, 1998). These claims fully encompass the assay that was described in Figure 3 on page 621 of MacLennan et al. Each of the receptors identified therein as "CB_1" and "CB_2" are "wild-type" and are "constitutively active" as indicated by the fact that the data presented in that figure are presented as a % change in a basal activity.

9) Claim 31 is rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. This claim encompasses an isolated human CB1 receptor having its native amino acid sequence. The text on page 11 of the instant specification indicates that isolated native human CB! was known in the art before the making of the instant invention and was not the invention of Applicant.

10) Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
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